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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,687	07/31/2003	Phillip Mark Hogarth	4602AR-2	2688
22442	7590	04/24/2006	EXAMINER	
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,687

Applicant(s)

HOGARTH ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-94 is/are pending in the application.
- 4a) Of the above claim(s) 67-73, 76, 80 and 82-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74, 75, 77-79 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/2/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III is acknowledged. The traversal is on the ground(s) that the method of using and making the elected product should be rejoined. The methods including all of the limitation of the allowable product would be rejoined when all of the elected claims are found to be allowable.

Claims 67-73 and 82-94 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 76 and 80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 67-83 are pending. Claims 74, 75, 77-79, and 81 are examined on merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74, 75, 77-79, and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Peltz et al., The Journal of Immunology, vol. 141, pages 1891-1896.

Claims 74, 75, 77-79, and 81 are drawn to an isolated polypeptide comprising an extracellular region of a native FcγRII receptor and a fusion component, wherein a

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fusion component is a carbohydrate in claim 76, the polypeptide is soluble in claim 77, in pharmaceutical diluent.

Peltz et al., "sFcγRII is a secreted protein containing the extracellular domain of FcγRII" at page 1983, right column, 1st paragraph, an isolated polypeptide comprising an extracellular region of a native FcγRII receptor in HEPES-saline at page 1892, right column, sFcγRII at 26 kDa seen at Fig. 2 (page 1893) is N-linked "carbohydrates".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peltz et al., (cited above) in view of Yeh et al., Proc. Natl. Acad. Sci. 1992 Mar 1;89(5):1904-8.

Claim 75 and 79 are interpreted as drawn to a polypeptide comprising an extracellular region of a native FcγRII receptor linked to human serum albumin (HSA).

As stated above, Peltz et al., teach a polypeptide comprising an extracellular region of a native FcγRII receptor.

Peltz et al., do not teach HSA.

However, Yeh et al., teach HAS has remarkably long half-life, together with its wide in vivo distribution and its lack of enzymatic or immunological functions" and

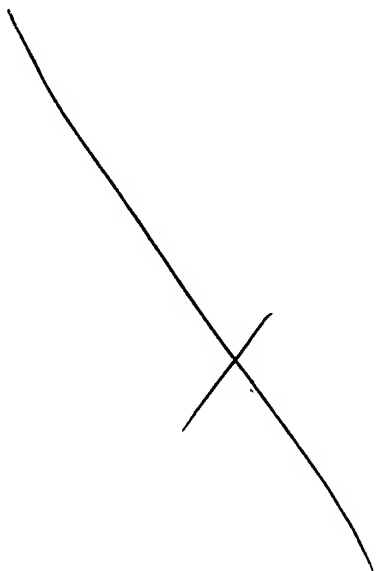
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therefore "fusion of bioactive peptides to HAS is a plausible approach toward the design and recovery" of secreted therapeutic.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine the teachings of Peltz et al., and Yeh et al., to arrive at the fusion of soluble Fc γ RII linked to HAS as taught by Yeh et al. with a reasonable expectation of success. One of ordinary skill would have been motivated to make the claimed fusion protein given the advantage of the fusion protein as stated in Yeh et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A large handwritten 'X' mark, likely indicating the end of the document or a specific administrative action.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Misook Y', with a stylized flourish at the end.

MISOOK YU, Ph.D.
Primary Examiner
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